

Demographics						
Country	Age (y)	Sex	Race	Ethnicity	Planned Arm	Actual Arm
USA	63	F	WHITE	HISPANIC OR LATINO	Placebo	Placebo

Subject Visits		
Visit	Visit Day	Visit Date
SCREENING 1	-7	2013-12-26
SCREENING 2	-1	2013-12-31
BASELINE	1	2014-01-02
AMBUL ECG PLACEMENT	13	2014-01-14
WEEK 2	14	2014-01-16
WEEK 4	28	2014-01-30
AMBUL ECG REMOVAL	30	2014-02-01
WEEK 6	42	2014-02-12
WEEK 8	56	2014-03-05
WEEK 12	84	2014-03-26
WEEK 14 (T)	98	2014-04-09
WEEK 16	112	2014-05-07
WEEK 20	140	2014-05-21
WEEK 22 (T)	154	2014-06-04
WEEK 24	168	2014-06-18
WEEK 26	182	2014-07-02

Adverse Events									
Sponsor Defined Identifier and Verbatim Term	Start Date (Day)	End Date (Day)	Serious?	Duration (days)	Severity	Relationship	Outcome	Action Taken	Treatment Emergent?
E06: DIARRHOEA	2014-01-09 (8)	2014-01-11 (10)	No	3	Mild	Remote	Recovered/Resolved		Yes
E07: APPLICATION SITE ERYTHEMA	2014-01-03 (2)		No	.	Mild	Probable	Not Recovered/Not Resolved		Yes
E08: APPLICATION SITE PRURITUS	2014-01-03 (2)		No	.	Mild	Probable	Not Recovered/Not Resolved		Yes

Vital Signs									
Vital Sign Parameter	SCR1	SCR2	BSLN	ECPL	WK02	WK04	ECRM	WK06	WK08
Diastolic BP (mmHg)	57	71	61	65	54	53	53	60	71
Pulse Rate (BEATS/MIN)	65	57	59	61	62	59	65	57	57
Systolic BP (mmHg)	147	145	131	146	132	132	123	138	140
Temperature (C)	36.1	36.1	36.2	35.9	36.5	36.1	36.4	36.3	36.7
Weight (kg)	54	.	54.4	.	53.1	54	.	53.1	53.1

Vital Signs				
WK12	WK16	WK20	WK24	WK26
64	66	63	71	55
52	61	58	56	59
138	152	136	137	129
36.3	36.6	36.3	36.5	36.2
53.1	53.1	53.1	53.1	53.5

